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applicable Federal and State laws related to fraud and abuse, including the physician self-referral prohibition (section 1877 of the Act) and the Federal anti kickback statute (section 1128B(b) of the Act).

[70 FR 4525, Jan. 28, 2005, as amended at 70 FR 67593, Nov. 7, 2005]

### § 423.160 Standards for electronic prescribing.

(a) *General rules.* (1) Part D sponsors must establish and maintain an electronic prescription drug program that complies with the applicable standards in paragraph (b) of this section when transmitting, directly or through an intermediary, prescriptions and prescription-related information using electronic media for covered Part D drugs for Part D eligible individuals.

(2) Except as provided in paragraph (a)(3) of this section, prescribers and dispensers that transmit, directly or through an intermediary, prescriptions and prescription-related information using electronic media must comply with the applicable standards in paragraph (b) of this section when e-prescribing for covered Part D drugs for Part D eligible individuals.

(3) *Exemptions.* (i) Entities transmitting prescriptions or prescription-related information by means of computer-generated facsimile are exempt from the requirement to use the NCPDP SCRIPT Standard adopted by this section in transmitting such prescriptions or prescription-related information.

(ii) Entities may use either HL7 messages or the NCPDP SCRIPT Standard to transmit prescriptions or prescription-related information internally when the sender and the recipient are part of the same legal entity. If an entity sends prescriptions outside the entity (for example, from an HMO to a non-HMO pharmacy), it must use the adopted NCPDP SCRIPT Standard or other applicable adopted standards. Any pharmacy within an entity must be able to receive electronic prescription transmittals for Medicare beneficiaries from outside the entity using the adopted NCPDP SCRIPT Standard. This exemption does not supersede any HIPAA requirement that may require

the use of a HIPAA transaction standard within an organization.

(iii) Entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider (such as a nursing facility) that in turn forwards the prescription to a dispenser are exempt from the requirement to use the NCPDP SCRIPT Standard adopted by this section in transmitting such prescriptions or prescription-related information.

(4) In accordance with section 1860D–4(e)(5) of the Act, the standards under this paragraph (b) of this section supersede any State law or regulation that—

(i) Is contrary to the standards or restricts the ability to carry out Part D of Title XVIII of the Act; and

(ii) Pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered Part D drugs under Part D of Title XVIII of the Act.

(b) *Standards.* (1) Entities described in paragraph (a) of this section must comply with the following adopted standards for transactions under this section:

(i) Before April 1, 2009 the standards specified in paragraphs (b)(2)(i) and (b)(3) of this section.

(ii) On or after April 1, 2009, the standards specified in paragraphs (b)(2)(ii) and (b)(3) through (b)(6) of this section.

(2) *Prescription.* (i) The National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide, Version 5, Release 0, (Version 5.0) May 12, 2004 (incorporated by reference in paragraph (c)(1)(iv) of this section), or the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, (Version 8.1) October 2005 (incorporated by reference in paragraph (c)(1)(i) of this section), to provide for the communication of a prescription or prescription-related information between prescribers and dispensers, for the following:

(A) Get message transaction.

(B) Status response transaction.

(C) Error response transaction.

- (D) New prescription transaction.
- (E) Prescription change request transaction.
- (F) Prescription change response transaction.
- (G) Refill prescription request transaction.
- (H) Refill prescription response transaction.
- (I) Verification transaction.
- (J) Password change transaction.
- (K) Cancel prescription request transaction.

(L) Cancel prescription response transaction.

(ii) The National Council for the Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT standard, Implementation Guide, Version 8, Release 1 (Version 8.1) October 2005 (incorporated by reference in paragraph (c)(1)(i) of this section), to provide for the communication of a prescription or prescription-related information between prescribers and dispensers, for the following:

- (A) Get message transaction.
- (B) Status response transaction.
- (C) Error response transaction.
- (D) New prescription transaction.
- (E) Prescription change request transaction.
- (F) Prescription change response transaction.
- (G) Refill prescription request transaction.
- (H) Refill prescription response transaction.
- (I) Verification transaction.
- (J) Password change transaction.
- (K) Cancel prescription request transaction.
- (L) Cancel prescription response transaction.
- (M) Fill status notification transaction.

(3) *Eligibility.* (i) The Accredited Standards Committee X12N 270/271-Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, A1, October 2002, Washington Publishing Company, 004010X092A1 (incorporated by reference in paragraph (c)(2)(i) of this section), for transmitting eligibility inquiries

and responses between prescribers and Part D sponsors.

(ii) The National Council for Prescription Drug Programs Telecommunication Standard Specification, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, for the NCPDP Data Record in the Detail Data Record (incorporated by reference in paragraph (c)(1)(iii) of this section), for transmitting eligibility inquiries and responses between dispensers and Part D sponsors.

(4) *Medication history.* The National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1 (Version 8.1), October 2005 (incorporated by reference in paragraph (c)(1)(i) of this section) to provide for the communication of Medicare Part D medication history information among Medicare Part D sponsors, prescribers, and dispensers.

(5) *Formulary and benefits.* The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0 (Version 1.0), October 2005 (incorporated by reference in paragraph (c)(1)(ii) of this section) for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors.

(6) *Provider identifier.* The National Provider Identifier (NPI), as defined at 45 CFR 162.406, to identify an individual health care provider to Medicare Part D sponsors, prescribers and dispensers, in electronically transmitted prescriptions or prescription-related materials for Medicare Part D covered drugs for Medicare Part D eligible individuals.

(c) *Incorporation by reference.* The Director of the Federal Register approves, in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51, the incorporation by reference of certain publications into this section. You may inspect copies of these publications at the headquarters of the Centers for Medicare & Medicaid Services (CMS), 7500 Security Boulevard, Baltimore,

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Maryland 21244, Monday through Friday from 8:30 a.m. to 4 p.m. or at the National Archives and Records Administration (NARA). For more information on the availability of this material at NARA, call (202) 741-6030, or go to [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html). The publications approved for incorporation by reference and their original sources are as follows:

(1) National Council for Prescription Drug Programs, Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260-7518; Telephone (480) 477-1000; and Facsimile (480) 767-1042 or <http://www.ncdp.org>.

(i) National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, October 2005.

(ii) The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0, October 2005.

(iii) National Council for Prescription Drug Programs Telecommunication Standard Specification, Version 5, Release 1 (Version 5.1), September 1999 and equivalent National Council for Prescription Drug Programs (NCPDP) Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record.

(iv) National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide, Version 5, Release 0, May 12, 2004, excluding the Prescription Fill Status Notification Transaction (and its three business cases; Prescription Fill Status Notification Transaction—Filled, Prescription Fill Status Notification Transaction—Not Filled, and Prescription Fill Status Notification Transaction—Partial Fill).

(2) Accredited Standards Committee, 7600 Leesburg Pike, Suite 430, Falls Church, VA 22043; Telephone (301) 970-4488; and Facsimile: (703) 970-4488 or <http://www.x12.org>.

(i) Accredited Standards Committee (ASC) X12N 270/271-Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010A1, October 2002, Washington Publishing Company, 004010X092A1.

(ii) [Reserved]

Authority: Section 1860D-4(e) of the Social Security Act (42 U.S.C. 1395w-104(e))

[70 FR 67593, Nov. 7, 2005, as amended at 71 FR 36023, June 23, 2006; 72 FR 66405, Nov. 27, 2007; 73 FR 18941, Apr. 7, 2008]

EFFECTIVE DATE NOTE: At 72 FR 66405, Nov. 27, 2007, § 423.160 was amended by revising paragraph (a)(3)(i), redesignating paragraphs (a)(3)(ii) and (iii) as (a)(3)(iii) and (iv) and adding a new paragraph (a)(3)(ii), effective January 1, 2009. For the convenience of the user, the added text is set forth as follows:

### § 423.160 Standards for electronic prescribing.

(a) \* \* \*

(3) \* \* \*

(i) Entities transmitting prescriptions or prescription-related information by means of computer-generated facsimile are exempt from the requirement to use the NCPDP SCRIPT Standard adopted by this section in transmitting such prescriptions or prescription-related information until January 1, 2009;

(ii) After January 1, 2009, electronic transmission of prescriptions or prescription-related information by means of computer-generated facsimile is only permitted in instances of temporary/transient transmission failure and communication problems that would preclude the use of the NCPDP SCRIPT Standard adopted by this section.

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### § 423.162 Quality improvement organization activities.

(a) *General rule.* Quality improvement organizations (QIOs) are required to offer providers, practitioners, and Part D sponsors quality improvement assistance pertaining to health care services, including those related to prescription drug therapy, in accordance with contracts established with the Secretary.

(b) *Collection of information.* Information collected, acquired, or generated by a QIO in the performance of its responsibilities under this section is subject to the confidentiality provisions of